

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: VALKIRS et al.  
Title: DIAGNOSTIC MARKERS OF  
STROKE AND CEREBRAL  
INJURY AND METHODS OF  
USE THEREOF  
Appl. No.: 10/714,078  
Filing Date: 11/14/2003  
Examiner: Cook, Lisa V.  
Art Unit: 1641  
Confirmation 2621  
Number:

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment-IDS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

§1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

### **RELEVANCE OF EACH DOCUMENT**

All of the documents are in English or have an English abstract.

Some of the documents being submitted were cited in a Supplementary European Search Report dated August 9, 2006 related to European Application 04760003.6-2404 and on a form PTO 892 by the Examiner assigned to U.S. Application No. 10/419,059 filed 4/17/03, U.S. Application No. 10/645,874 filed 8/20/03 and U.S. Application No. 10/673,077 filed 9/26/03. Other citations were cited in the International Search Report for International Application No. PCT/US05/32287 filed September 9, 2005.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

**STATEMENT**

Fees in the amount of \$180.00 in accordance with 37 CFR §1.17(p) to cover the fee associated with an information disclosure statement under 37 CFR §1.97(c) are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 06/18/2007

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By Barry S. Wilson

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Attorney for Applicant

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| Substitute for form 1449/PTO<br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |   |    |   | <b>Complete if Known</b> |                   |
|  |   |    |   | Application Number       | 10/714,078        |
|  |   |    |   | Filing Date              | 11/14/2003        |
|  |   |    |   | First Named Inventor     | Gunars E. Valkirs |
|  |   |    |   | Art Unit                 | 1641              |
|  |   |    |   | Examiner Name            | Cook, Lisa V.     |
| Sheet  | 1 | of | 2 | Attorney Docket Number   | 071949-5408       |

### U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|--|
|                    |                       | Number-Kind Code <sup>2</sup> (if known) |                                |  |  |
|                    | A1                    | 5,028,535                                | 07/02/1991                     | Buechler et al.                                    |  |
|                    | A2                    | 6,117,644                                | 09/12/2000                     | Debold   |  |
|                    | A3                    | 6,124,430                                | 09/26/2000                     | Mischak et al.                                     |  |
|                    | A4                    | 2004/0167341                             | 08/2004                        | Haffner  |  |

### UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | U.S. Patent Application Document                | Filing Date of<br>Cited Document<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
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### FOREIGN PATENT DOCUMENTS

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|--------------------|-----------------------|---|--------------------------------|---|--|----------------|
|                    |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |   |  |                |
|                    | A5                    | WO 00/18801   | 04/16/2000                     | Ronn et al.   |  |                |
|                    | A6                    | WO 02/089657  | 11/14/2002                     | Biosite, Inc.                                       |  |                |
|                    | A7                    | WO 01/14885   | 03/01/2001                     | Biomedica Gesellschaft MBH                          |  |                |

### NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>6</sup> |
|--------------------|-----------------------|--|----------------|
|                    | A8                    | Supplementary European Search Report - part of Communication dated August 9, 2006 for EP Application No. 04760003,6-2404.  |                |
|                    | A9                    | Allwords.com., Definition of "Appreciable"   |                |
|                    | A10                   | GREENBERG "Drug News and Perspectives", 1998, Vol. 11, No. 5, pp.265-70 (Abstract Only).   |                |
|                    | A11                   | HUNTER et al., "Analysis of Peptides Derived from Pro Atrial Natriuretic Peptide That Circulate in Man an Increase in Heart Disease", Scand J. Clin Lab Invest 56, 205-216 (1998)  |                |
|                    | A12                   | INDIK and ALPERT, Detection of pulmonary embolism by D-dimer assay, spiral computed tomography, and magnetic resonance imaging. Prog. Cardiovasc. Dis. 42:261-272, 2000  |                |

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| Examiner Signature |  | Date Considered |  |
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| Sheet  | 2 | of | 2 | Attorney Docket Number   | 071949-5408       |

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| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.                                    | T <sup>6</sup> |
|                                 | A13                   | MILLS et al., "Sustained Hemodynamic Effects of an Infusion of Nesiritide (Human b-Type Natriuretic Peptide) in Heart Failure", Journal of the American College of Cardiology, Vol. 34, No. 1, pp155-62 (1999)  |                |
|                                 | A14                   | MULLINS et al., CT and conventional and diffusion-weighted MR imaging in acute stroke: Study in 691 patients at presentations to the emergency department. Radiology, 224(2): 353-360, 2002.  |                |
|                                 | A15                   | NAKAGAWA et al., Plasma concentrations of brain natriuretic peptide in patients with acute ischemic stroke. Cerebrovasc Disease, 19:157-164, 2005.  |                |
|                                 | A16                   | NG and ILAG, Biomedical applications of protein chips. J. Cell. Mol. Med., 6:329-340, 2002  |                |
|                                 | A17                   | "Tumor necrosis factor ligand superfamily member 12." Human Protein Reference Database, <a href="http://www.hprd.org/alternate?protein=04074&amp;isoform_id=04074_1&amp;isoform_name=Isoform_1">http://www.hprd.org/alternate?protein=04074&amp;isoform_id=04074_1&amp;isoform_name=Isoform_1</a> |                |
|                                 | A18                   | VENUGOPAL, "Cardiac Natriuretic Peptides – Hope or Hype?", Journal of Clinical Pharmacy and therapeutics, Vol. 26, No. 1, 15-31 (2001)  |                |
|                                 | A19                   | VESLEY et al., "Negative Feedback of Atrial Natriuretic Peptides", Journal of Clinical Endocrinology and Metabolism, Vol. 78, No. 5, 1128-1134 (1994)   |                |
|                                 | A20                   | YIP et al., Time course and prognostic value of plasma levels of N-terminal pro-brain natriuretic peptide in patients after ischemic stroke. Circulation Journal, 70:447-452, 2006.   |                |

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